

JUL 18 2019

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FORT SMITH DIVISION

DOUGLAS F. YOUNG, Clerk
By
Deputy Clerk

UNITED STATES OF AMERICA,

Plaintiff,

v.

24 CASES (SIXTEEN, 18.7 OZ. BOXES PER
CASE) MORE OR LESS, OF RAISIN BRAN CEREAL,
AN ARTICLE OF FOOD, *et al.*

Civil No. 18-2188 PKH

Defendant Articles *in rem*,

and

J AND L GROCERY, LLC, a corporation,
and JAMES T. WHITE and LORI A.
LAYNE, individuals,

Defendants.

CONSENT DECREE OF CONDEMNATION AND PERMANENT INJUNCTION

On November 7, 2018, a Complaint for Forfeiture against the above-captioned articles was filed in this Court on behalf of the United States of America by its attorneys for the Western District of Arkansas. The Complaint alleges that the articles proceeded against are articles of food, drug, device, and cosmetic within the meaning of the Federal Food, Drug, and Cosmetic Act (the “Act”), 21 U.S.C. §§ 301-399i, that are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. §§ 342(a)(4), 351(a)(2)(A), and 361(c), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered

injurious to health. The Complaint additionally alleges that the defendant articles of drug are also adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the facilities or controls used for their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety, and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

Pursuant to the Warrant for Arrest issued by this Court, the United States Marshals Service (the “USMS”) for this District seized the articles on November 7 and 8, 2018.

Thereafter, notice of the complaint and seizure were published in accordance with the applicable rules of this Court.

On November 9, 2018, J and L Grocery, LLC (“J&L” or “Claimant”) intervened and filed a claim to the seized articles. On June 14, 2019, the United States amended the Complaint to seek injunctive relief and add J&L, J&L’s owner, James T. White, and J&L’s manager, Lori A. Layne (collectively “Defendants”) as parties.

Defendants now consent to the entry of this Decree without contest, before any testimony has been taken.

Whereupon, the Court being fully advised, it is on motion of the parties hereto,
ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1395.

SEIZURE PROVISIONS

2. Claimant affirms that it is the sole owner of the seized articles of food, drug, device, and cosmetic and that no other person has an interest in the goods.

3. The seized articles are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. §§ 342(a)(4), 351(a)(2)(A), or 361(c), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health. The seized articles of drug are also adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety, and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

4. The seized articles are hereby condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

5. Pursuant to 21 U.S.C. § 334(e), the United States of America shall recover from the Claimant all court costs and fees, storage and other proper expenses already incurred with respect to the condemned articles, and such additional expenses as may hereafter be incurred and taxed pursuant to the authority set forth in 21 U.S.C. § 334. Claimant shall pay these costs within sixty (60) calendar days after receiving notice of such costs from the United States Food and Drug Administration (“FDA”), the USMS, and/or the United States Department of Justice (“DOJ”).

6. Within twenty (20) calendar days after entry of this Decree, Claimant shall execute and file with the Clerk of this Court a good and sufficient penal bond with surety, in a form acceptable to the Clerk of this Court and payable to the United States of America, in the amount of forty thousand dollars (\$40,000.00), conditioned on the Claimant's abiding by and performing all of the terms and conditions of this Decree with respect to the condemned articles and such further Decrees or Orders as may be entered in this proceeding with respect to the condemned articles. The bond shall be applied to Lot 1 as defined in the Destruction Plan to be submitted and approved under paragraph 8 of this Decree and held for application to each successive lot as defined in the Destruction Plan.

7. Claimant shall provide all necessary documentation in its possession, custody, or control to verify to FDA's satisfaction the content and value of each lot of the condemned articles of food (including dietary supplements), drug, medical device, and cosmetic.

8. After filing of the bond with this Court, the Claimant shall give written notice to the FDA Dallas District Office pursuant to paragraph 29, that Claimant, at its own expense, is prepared to destroy the condemned articles under the supervision of the USMS and a duly authorized representative of FDA. Claimant shall not commence, permit any other person to commence, or cause any other person to commence destroying the condemned articles unless and until Claimant: (a) submits a written statement to FDA detailing Claimant's proposed plan to destroy the condemned articles (the "Destruction Plan"), including a schedule for the destruction; (b) receives written approval of the Destruction Plan from FDA; (c) receives written authorization from FDA to commence destroying the condemned articles under the supervision of FDA; and (d) has fully paid the costs and fees pursuant to paragraph 5. Claimant shall submit its Destruction Plan to FDA within thirty (30) calendar days after filing its bond with the Court.

9. The Claimant shall at all times, until the condemned articles have been destroyed

pursuant to paragraphs 8 and 10, retain intact each lot of condemned articles for examination or inspection by FDA and the USMS, and shall maintain the records or other proof necessary to establish the identity of the articles comprising each lot to the satisfaction of FDA and the USMS.

10. If the Destruction Plan is approved by FDA pursuant to paragraph 8, the USMS for this District shall successively release each specified lot of the condemned articles to the Claimant for the sole purposes of destroying such articles pursuant to the Destruction Plan. After release of the first lot, subsequent lots shall be released by the USMS to the Claimant for the sole purposes of destruction pursuant to the Destruction Plan, if and only if Claimant complies with all of the terms of this Decree with respect to each previously-released lot, and each such lot has been successfully destroyed. Under no circumstance shall FDA's silence be construed as a substitute for written approval or acceptance of Claimant's destruction of the lot.

11. Within two (2) months of receiving approval of the Destruction Plan, Claimant shall complete the process of destroying the condemned articles under the supervision of FDA and the USMS. Unless an extension of time is mutually agreed to in writing by FDA and the Claimant.

12. If Claimant breaches any condition of this Decree or in any subsequent Decree or Order in this proceeding with respect to the condemned articles, Claimant shall immediately return the condemned articles to the USMS for this District at Claimant's expense or shall otherwise dispose of them at its own expense and under the direct supervision of an FDA representative pursuant to an Order of this Court. In the event that return of any of the condemned articles becomes necessary pursuant to this paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by the United States.

13. Claimant shall not dispose of the condemned articles or any part of them in a

manner contrary to the provisions of the Act, or other laws of the United States, or of any State or Territory (as defined in the Act), in which they are sold or disposed.

14. Claimant shall reimburse the United States of America for the cost of supervision, inspection, review, examination, and analyses conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, these rates are: \$97.57 per hour and fraction thereof per representative for inspection and supervision work; \$132.89 per hour and fraction thereof per representative for laboratory and analytical work; \$0.58 per mile for travel expenses for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate for subsistence expenses, where necessary. In the event that the standard rates generally applicable to USMS or FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be increased or decreased without further order of the Court. Claimant shall pay any such costs within ten (10) calendar days after being presented with an invoice for such costs from the FDA, the USMS, and/or the DOJ.

15. In the event Claimant does not avail itself, in the manner and within the timeframes stated in this Decree, of the opportunity to: (1) post a good and sufficient penal bond with surety with this Court; (2) submit a Destruction Plan for the condemned articles to FDA; or (3) destroy the condemned articles within two (2) months of the approval of the Destruction Plan, unless that time is extended by mutual consent, the USMS for this District shall destroy the condemned articles and make due return to this Court regarding their disposition. Claimant shall bear the costs of storage and destruction that are incurred by the United States pursuant to this paragraph and shall pay such costs within ten (10) calendar days of receiving an invoice from FDA, the USMS, or DOJ.

16. Should the Claimant fail to abide by and perform all the terms and conditions of

this Decree or any such further Decree or Order as may be entered in this proceeding with respect to the condemned articles, then said bond shall, in its entirety, on motion of the United States of America in this proceeding, be forfeited to the United States of America and judgment entered thereon, and any condemned articles remaining in the custody of the USMS shall be forfeited and disposed of pursuant to further Order of the Court.

17. The United States Attorney for this District, upon being advised by FDA that the conditions of this Decree have been performed with respect to the condemned articles and that Claimant has paid all costs submitted to Claimant as of that date, shall transmit such information to the Clerk of this Court, whereupon the bond shall be cancelled and discharged.

INJUNCTIVE PROVISIONS

18. Defendants represent to the Court that, going forward, they no longer intend to receive, hold for sale, or distribute, at or from any location, drugs, devices, cosmetics, and dietary supplements, as defined by 21 U.S.C. § 321(g)-(i) and (ff). Defendants further represent that they no longer intend to receive, hold for sale, or distribute food, as defined in 21 U.S.C. § 321(f), at or from any building at their facility at 4810 N. Highway 71, Alma, Arkansas other than the grocery store and the pricing shed. If Defendants later intend to resume receiving, holding for sale, and/or distributing drugs, devices, cosmetics, and dietary supplements at or from any location, they must notify FDA in writing and comply with paragraph 21. If Defendants later intend to resume receiving, holding for sale, and/or distributing food at or from any building at their facility at 4810 N. Highway 71, Alma, Arkansas other than the grocery store and the pricing shed, they must first notify FDA in writing and comply with paragraph 20.

19. Immediately upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who have received actual notice of

this Decree, are prohibited from, directly or indirectly, receiving, holding for sale, or distributing any article of food (excluding dietary supplements) at or from the grocery store and pricing shed at their facility at 4810 N. Highway 71, Alma, Arkansas, unless and until Defendants:

A. Establish and implement a written sanitation control program for the grocery store and pricing shed, which shall set out the details for sanitation control over those facilities and processes used to receive, prepare, pack, hold, and distribute articles of food, and all handling and storage equipment therein. The written sanitation control program shall be designed to ensure that the facilities used to receive, prepare, pack, hold, or distribute articles of food and all equipment therein are maintained continuously in a sanitary condition to prevent conditions under which articles of food may become contaminated with filth and/or may be rendered injurious to health or otherwise adulterated. The written sanitation control program must be approved in writing by FDA prior to implementation. Defendants shall assign responsibility for the implementation of the written sanitation control program to a person or persons who, by reason of education, training, and experience in sanitation work, are competent to maintain the facilities and all equipment therein in sanitary condition. Implementation of the written sanitation control plan shall include training for all J&L employees to ensure they are aware of the contents and requirements of the written sanitation control plan;

B. Retain, at Defendants' expense, an independent pest control company having no personal or financial ties (other than a retention agreement) to Defendants or their families, and which, by reason of background, education, training, and experience, is qualified to inspect and perform pest control services for J&L. Defendants shall ensure that the pest control company inspects Defendants' grocery store and pricing shed and surrounding grounds on a frequent and ongoing basis to ensure that birds, cats, rodents, insects, and other pests are not present in those facilities. Any reports prepared by the pest control company shall be provided

to FDA within three (3) calendar days of receipt;

C. Thoroughly clean, renovate, and render Defendants' grocery store and pricing shed used to receive, prepare, pack, hold, or distribute articles of food and all equipment therein sanitary and fit for use in packaging, holding, and distributing articles of food and have in place adequate procedures to ensure that the grocery store and pricing shed and all equipment therein are maintained continuously in such condition;

D. Remove from Defendants' grocery store and pricing shed and all equipment therein birds, cats, rodents, insects, other pests, and filth contributed by them, and microbial and physical contaminants, and adequately repair the floors, walls, windows, doors, and building in order to prevent birds, cats, rodents, insects, other pests from entering those facilities;

E. Establish adequate methods and controls for packaging, holding, and distributing articles of food in the grocery store and pricing shed that are designed to ensure that articles of food do not become contaminated by pests, or with filth, or microbial or physical contaminants;

F. Report in writing to FDA at the address provided in paragraph 29 the steps that Defendants have taken to comply with the terms of subparagraphs A-E of this paragraph;

G. If FDA deems necessary, FDA inspects the J&L's facility in order to determine whether the grocery store and pricing shed, articles of food, and sanitation control program are in compliance with the Act, applicable regulations, and this Decree. The cost of all such inspections shall be borne by Defendants at the rates specified in paragraph 14; and

H. Receive written notification from FDA stating that Defendants appear to be in compliance with the Act, all applicable regulations, and this Decree, and authorizing Defendants to resume receiving, holding for sale, and distributing articles of food (excluding

dietary supplements) at or from Defendants' grocery store and pricing shed.

20. Immediately upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree, are prohibited from directly or indirectly doing or causing any of the following actions: receiving, holding for sale, or distributing any article of food (excluding dietary supplements) at or from any building at their facility at 4810 N. Highway 71, Alma, Arkansas, 72921, other than the grocery store and pricing shed. After Defendants receive the notification in paragraph 19.H with respect to the grocery store and pricing shed, if Defendants wish to receive, hold for sale, or distribute any article of food (excluding dietary supplements) at or from any building other than the grocery store and pricing shed, they shall give sixty (60) days notice to FDA, complete the actions set forth in paragraph 19.A-19.F with respect to that building, and receive written notification from FDA stating that Defendants appear to be in compliance with the Act, all applicable regulations, and this Decree, and authorizing Defendants to resume receiving, holding for sale, and distributing articles of food (excluding dietary supplements) at or from that building. If FDA deems necessary, FDA may inspect J&L's facility in order to determine whether the buildings identified pursuant to this paragraph, articles of food, and sanitation control program are in compliance with the Act, applicable regulations, and this Decree. The cost of all such inspections shall be borne by Defendants at the rates specified in paragraph 14.

21. Immediately upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree, are prohibited from directly or indirectly doing or causing any of the

following actions: receiving, holding for sale, or distributing any article of drug, device, cosmetic, and/or dietary supplement, at or from any location, unless and until Defendants:

A. Notify FDA in writing sixty (60) days in advance of their intent to receive, hold for sale, and/or distribute any article of drug, device, cosmetic, and/or dietary supplement and the buildings they intend to use for such activities;

B. If FDA has not already issued written authorization to resume food operations at the building(s) identified in paragraph 21.A pursuant to paragraph 19.H or paragraph 20, complete all the actions set forth in paragraph 19.A-19.F with respect to such buildings;

C. Establish adequate facilities and controls (including temperature controls) for packaging, holding, testing, or distributing articles of drug for any and all buildings identified in paragraph 21.A to ensure that articles of drug received, held, and/or distributed from such buildings are in conformity with current good manufacturing practice, including 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. § 211.208;

D. Establish adequate facilities and controls (including temperature controls) for packaging, holding, testing, and distributing articles of drug, device, cosmetic, and/or dietary supplement that ensure such articles do not become adulterated under the Act;

E. Report in writing to FDA at the address provided in paragraph 29 that Defendants have fully complied with the terms of subparagraphs A-D of this paragraph;

F. If FDA deems necessary, FDA inspects J&L's facility in order to determine whether the buildings identified in paragraph 21.A., facilities and controls are in compliance with the Act, applicable regulations, and this Decree. The cost of any such inspections shall be borne by Defendants at the rates specified in paragraph 14; and

G. Receive written notification from FDA stating that Defendants appear to be in compliance with the Act, all applicable regulations, and this Decree, and authorizing Defendants

to resume receiving, holding for sale, and distributing articles of drug, device, cosmetic, and/or dietary supplement at or from buildings identified under paragraphs 21.A.

22. Upon entry of this Decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that violates the Act, 21 U.S.C. § 331(k), by causing articles of food, drug, device, and/or cosmetic to be adulterated within the meaning of 21 U.S.C. §§ 342(a)(4), 351(a)(2)(A), 351(a)(2)(B), or 361(c), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

23. Within thirty (30) calendar days after FDA has notified Defendants in writing pursuant to paragraph 19.H that they may resume food (excluding dietary supplements) operations or paragraph 21.G that they may resume drug, device, cosmetic, and/or dietary supplement operations:

A. Defendants shall retain at their own expense, an independent person or persons (the “Auditor”) to conduct audit inspections of Defendants’ facilities not less than once every six (6) months for a period of one year and not less than once every twelve (12) months for a period of two years thereafter, for a total of three (3) years of auditing. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement entered into by the parties) to any of the Defendants, any of J&L’s officers or employees, or their immediate families. Defendants shall notify FDA of the Auditor’s qualifications in writing as soon as the Auditor is retained.

B. The audit inspection shall evaluate and address all FDA inspection

observations of deficiencies from August 7, 2018, to the present and to determine whether Defendants are in compliance with the written sanitation control program and the Act and applicable regulations, and this Decree.

C. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the “Audit Report”) identifying in detail any deviations from the Act and applicable regulations (“Audit Report Observations”). As part of every Audit Report except the first Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Report shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date each audit inspection is completed. If an Audit Report contains any Audit Report Observations, FDA may, in its discretion, require that the three-year auditing cycle be extended by one year or until such Audit Report Observations have been corrected. In addition, Defendants shall maintain the complete Audit Reports and all of their underlying data in separate files at their facilities and shall make the Audit Reports and underlying data available to FDA promptly upon request.

D. If an Audit Report contains any Audit Report Observations, Defendants shall, within thirty (30) business days of receipt of the Audit Report, correct those observations, unless FDA notifies them that a shorter time period is necessary. If after receiving the Audit Report, Defendants believe that correction of an Audit Report Observation will take longer than thirty (30) business days, Defendants shall, within fifteen (15) business days of receipt of the Audit Report, propose to FDA a schedule for completing corrections (“Correction Schedule”) and provide justification describing why the additional time is necessary. FDA shall, within ten (10) business days of receiving the proposed Correction Schedule, review and approve or disapprove the Correction Schedule in writing. If FDA does not approve the Defendants’ first proposed

Correction Schedule, Defendants shall submit a revised Correction Schedule within three (3) business days of receiving notice of FDA's disapproval. FDA shall, within ten (10) business days of receiving the revised Correction Schedule, review and approve or disapprove the revised Correction Schedule in writing. If FDA does not approve Defendants' revised Correction Schedule, Defendants shall correct all Audit Report Observations within three (3) business days of receiving notice of FDA's disapproval, unless FDA notifies them in writing that a longer time period is acceptable. Defendants shall complete all corrections according to the approved Correction Schedule.

E. Within sixty (60) business days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within ten (10) business days of the completion of that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected.

24. If at any time after entry of this Decree, FDA determines, based on the results of an inspection, an Audit Report, or other information, that Defendants are not in compliance with the Act, applicable regulations, or this Decree with respect to their food (including dietary supplements), drug, device, or cosmetic products, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate corrective actions, including, but not limited to, the following:

A. Discontinue all packing holding, and distributing of food (including dietary supplements), drug, device, or cosmetic products at some or all of their facilities;

B. Recall, at Defendants' expense, any food (including dietary supplements), drug, device, or cosmetic product that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports of information to FDA; and/or

E. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations. Defendants shall immediately implement any and all measures under the paragraph as directed by FDA.

25. Should the United States bring, and prevail in, a civil or criminal contempt action arising out of the violation of any term of this Decree, Claimant shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative costs relating to such contempt proceedings.

26. Representatives of FDA shall be permitted, without prior notice and as and when the FDA deems necessary, to make inspections of Claimant's facilities, and, without prior notice, take any other measures necessary to monitor or ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to buildings, equipment, articles of food (including dietary supplements), drug, device, cosmetic, containers, and packaging material(s) therein; to take photographs and make video recordings; to take samples of articles of food (including dietary supplements), articles of drug, articles of device, articles of cosmetic, containers, and packaging material(s); to examine and copy all records relating to the packaging, holding, and distributing of any and all articles of food (including dietary supplements), drug, device, or cosmetic and/or relating to the sanitation of the facilities. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to,

the authority to make inspections under the Act, 21 U.S.C. § 374. The cost of all such inspections shall be borne by Defendants at the rates specified in paragraph 14.

27. If Defendants fail to comply with the provisions of this Decree, Defendants shall pay to the United States of America liquidated damages in the sum of five hundred dollars (\$500.00) for each day that Defendants fail to comply with this Decree and an additional five hundred dollars (\$500.00) for each shipment or sale of food (including dietary supplements), drug, device, or cosmetic that fails to comply with this Decree. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.


28. Claimant shall abide by the decisions of FDA and its representatives with respect to this Decree, which decisions shall be final. All decisions specified in this Decree shall be vested in FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by a court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record that was before FDA at the time of the decision. No discovery shall be authorized or allowed by either party.

29. All notifications, correspondence, and communications to FDA required by this Decree: (a) shall be addressed to the Director, Dallas District Office, U.S. Food and Drug Administration, Department of Health and Human Services, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204; (b) shall reference the civil action number; and, (c) shall be prominently marked "J and L Grocery, LLC Consent Decree Correspondence."

30. Defendants shall notify FDA in writing at least thirty (30) calendar days before any change in location, ownership, or character of their business, such as reorganization, dissolution, assignment, or sale resulting in the emergence of a successor corporation or business entity, the creation or dissolution of subsidiaries, or any other change in the corporate or business structure of any newly-formed business entity (including any “doing business as” entity) over which Defendants have authority, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any successor or assignee at least thirty (30) calendar days prior to assignment or change in ownership. Defendants shall furnish FDA with an affidavit of compliance with this paragraph at least thirty (30) calendar days prior to such assignment or change in ownership.

31. The Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.


IT IS SO ORDERED this 18th day of JULY, 2019.

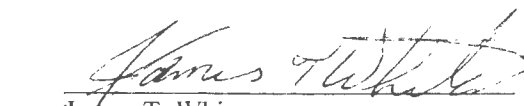


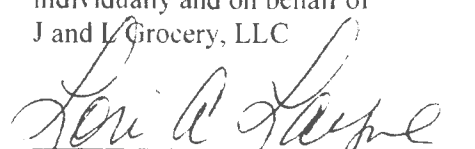
P.K. HOLMES, III
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree.

FOR THE DEFENDANTS:



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James T. White,
individually and on behalf of
J and L Grocery, LLC


Lori A. Layne, Manager,
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FOR THE UNITED STATES:

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